



**The effect of the FIFA 11 prevention programmes on the overall injury rate in football**  
*a systematic review and meta-analysis*

Thorborg, K.; Krommes, K.; Esteve, E.; Clausen, M. B.; Bartels, E. M.; Rathleff, Michael Skovdal

*Publication date:*  
2016

*Document Version*  
Accepted author manuscript, peer reviewed version

[Link to publication from Aalborg University](#)

*Citation for published version (APA):*  
Thorborg, K., Krommes, K., Esteve, E., Clausen, M. B., Bartels, E. M., & Rathleff, M. S. (2016). *The effect of the FIFA 11 prevention programmes on the overall injury rate in football: a systematic review and meta-analysis.* (version 1.1 ed.)

**General rights**

Copyright and moral rights for the publications made accessible in the public portal are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.

- Users may download and print one copy of any publication from the public portal for the purpose of private study or research.
- You may not further distribute the material or use it for any profit-making activity or commercial gain
- You may freely distribute the URL identifying the publication in the public portal -

**Take down policy**

If you believe that this document breaches copyright please contact us at [vbn@aub.aau.dk](mailto:vbn@aub.aau.dk) providing details, and we will remove access to the work immediately and investigate your claim.

# **STUDY PROTOCOL:**

## **THE EFFECT OF THE FIFA 11 PREVENTION PROGRAMMES ON THE OVERALL INJURY RATE IN FOOTBALL: A SYSTEMATIC REVIEW AND META-ANALYSIS**

Version changes

From 1.0 → 1.1 marked with **yellow**, and includes:

1. Changed number and date of the protocol version
2. Included extra affiliation for Ernest Esteve
3. Included extra affiliation for Michael Skovdal Rathleff
4. Changed literature search dates
5. Changed search strategy: warm up changed to warmup, as this is a more correct term. The search will not be updated after the analyses have been conducted, unless submission is severely delayed and the search can be considered outdated.
6. Made changes to “Implementation of statistical analyses plan” section. As Michael Skovdal Rathleff has appeared on a letter to the editor in December, 2015, together with the rest of the author group of the present study, concerning studies on FIFA prevention programmes, we can no longer consider him blinded to this kind of information during the statistical analyses. As Michael Rathleff cannot influence the data provided by each study, we do not consider this to bias the statistical analyses in any way, and Michael Rathleff will still be doing all the statistical analyses.

**STUDY PROTOCOL:**

**THE EFFECT OF THE FIFA 11 PREVENTION PROGRAMMES ON THE OVERALL INJURY RATE IN FOOTBALL: A SYSTEMATIC REVIEW AND META-ANALYSIS**

**AUTHORS:**

Thorborg K (1, 2) Krommes K (1, 2), Esteve E (1, 2, 3), Clausen MB (1,2,5), Bartels EM (6), Rathleff MS (7, 8, 9)

**AFFILIATIONS:**

(1) Department of Orthopaedic Surgery, Sports Orthopedic Research Center, Amager-Hvidovre Hospital, Faculty of Health Sciences, University of Copenhagen, Denmark

(2) Physical Medicine and Rehabilitation – Copenhagen (PMR-C), Amager-Hvidovre Hospital, Copenhagen University Hospital

(3) University School of Health and Sport, Universitat de Girona (EUSES-UdG), Girona, Spain.

(4) Sportclinic, Physiotherapy and Sports Training Center, Girona, Spain

(5) Bachelor's Degree Programme in Physiotherapy, Department of Physiotherapy and Occupational Therapy, Faculty of Health and Technology, Metropolitan University College, Copenhagen, Denmark

(6) The Parker Institute, Copenhagen University Hospital, Bispebjerg and Frederiksberg, Copenhagen, Denmark

(7) Center for Sensory-Motor Interaction, Department of Health Science and Technology, Aalborg University, Fredrik Bajers Vej 7E-1, Aalborg, Denmark

(8) Department of Occupational Therapy and Physiotherapy, Aalborg University Hospital, Soendre Skovvej 15, 9000 Aalborg, Denmark.

(9) Research Unit for General Practice in Aalborg and Department of Clinical Medicine, Aalborg University, Denmark

**CORRESPONDING AUTHOR:**

Kristian Thorborg, from Department of Orthopaedic Surgery, Sports Orthopedic Research Center, Amager-Hvidovre Hospital, Faculty of Health Sciences, University of Copenhagen, Denmark

**KEYWORDS:**

Football, Prevention, FIFA, Sports Injuries, Lower limb injuries

## INTRODUCTION

More than 265 million people around the world are estimated by Fédération Internationale de Football Association (FIFA) to participate regularly in football (soccer).<sup>1</sup> Football has been recognised, together with running, as one of the most promising sport and leisure time activities to induce important health benefits.<sup>2</sup> Football improves cardiovascular and metabolic health,<sup>2</sup> and prevent risk factors for lifestyle diseases such as diabetes and hypertension.<sup>3</sup> However, football includes an inherent risk of injury,<sup>4;5</sup> which is why injury prevention in football is crucial.<sup>6</sup> Not only does it keep people playing, it also makes it possible to achieve the health benefits associated with the game. Each year 5.8 million people are treated at the hospital due to injuries associated with sports.<sup>7</sup> Team ball sports account for 43% of all hospital-related sports treatment – and football accounts for the majority (67%) of these.<sup>7</sup> The FIFA Medical Assessment and Research Centre (F-MARC) recently decided to combine the direct health effects of playing the game with education and prevention, and has in connection with this created a comprehensive football-based health education programme called “11 for Health”.<sup>3;8</sup>

FIFA has since 2004 been focusing on strategies for injury prevention by introducing the FIFA 11 programme for injury prevention in football.<sup>9</sup> F-MARC developed and tested the FIFA 11 programme which has been applied in different areas of organised football to prevent and reduce injury among the many people participating in the sport at the amateur and grassroots level.<sup>6;9</sup> The programme includes specific strengthening, balancing and plyometric exercises, and is to be included during a structured warm-up session. It has been tested in different football cohorts with varying results.<sup>10</sup> Two variations of the 11 programme have been developed and provided by FIFA, the FIFA 11 and the FIFA 11+.<sup>10</sup> The FIFA 11+ is a revised version of the original FIFA 11 programme.<sup>10-12</sup> The FIFA 11+ includes similar key exercises as the FIFA 11 with minor additions, including a more dynamic warm-up and a more specific progression model for the included exercises, to allow for more variation and physical improvement.<sup>10-12</sup> In this way, it aims for optimising improvements in strength, balance and plyometric ability, which may lead to injury reduction.<sup>10-12</sup>

The reason for revising the 11 programme in 2006 was that the 11 programme was found unsuccessful in reducing injury based upon a single study.<sup>11;12</sup> However, a finding of no differences in injury estimates from a single study cannot be considered proof of no effect. Simply, this could be due to insufficient power to detect reductions in injury rates of less than the 40%, which the first FIFA 11 trial was powered to detect.<sup>12</sup> This means that relevant effects on injury reduction of less than 40% could potentially exist from the FIFA 11 programmes, but that an increased number of participants may be needed to detect such a difference. Pooling data from individual studies into a meta-analysis offer an opportunity to increase statistical power and test whether the FIFA programmes are associated with injury reduction, as originally hypothesized in the initial studies where FIFA was involved.<sup>10-12</sup>

With an increase over recent years in the number of studies investigating the preventive effect of the FIFA 11 programmes,<sup>10</sup> with the first study being initiated in 2004,<sup>9</sup> it now seems timely to address the important question: Is there a preventive (injury reducing) effect of the FIFA 11 programme on the overall injury rate in football players? Now, more than ever, this questions is of particular relevance, as it was recently proclaimed by Bizzini and Dvorak (2015) from the F-MARC group, in a narrative review in British Journal of Sports medicine,<sup>6</sup> that by “prioritising injury prevention through the 11+ programme leading to protecting a football player” overall health will be further pursued by FIFA and F-MARC through worldwide promotion of the FIFA 11+ prevention programme among the member associations. This with the specific strategic goal: “to prevent football injuries and to promote football as a health-enhancing leisure activity, improving social

behaviour".<sup>6</sup> While such a strategy is clearly relevant and appealing, it also relies on the premise that the FIFA 11 programmes are actually capable of reducing the overall number football injuries, which from individual studies does not seem to be a consistent finding in the existing literature.<sup>10</sup>

Thus, the primary objective of the present study is, based on available (published) studies, to investigate the effect, positive as well as negative, of the FIFA 11 prevention programmes compared with control interventions (no or sham interventions), on the overall injury rate in football.

We hypothesize that the FIFA 11 programmes will reduce the overall injury rate compared to control (no or sham intervention) in football.

## **METHODS**

### **Literature search**

We will conduct a systematic review following the PRISMA statement<sup>13</sup> and prospectively register the review in PROSPERO. We will carry out a systematic search in the following bibliographic databases: Medline via Pubmed, Embase via OVID, CINAHL via Ebsco, Web of Science, SportDiscus and Cochrane Central Register of Controlled Trials, from 2004 to the 14<sup>th</sup> of March 2016, as the FIFA 11 prevention programmes were initiated and implemented from 2004-2005.<sup>9;14</sup> A hand-search of the reference lists of relevant articles will also be conducted for other potential relevant references and FIFA - Medical Assessment and Research Centre (F-MARC) will be contacted to verify if any important FIFA 11 or FIFA 11+ studies/publications do not appear from the search. No restrictions on language will be included in the search.

The following search strategy was tested to be the most efficient across databases, and will be applied in all the databases mentioned above:

(fifa OR f-marc OR fmarc OR prevention program\* OR warm-up program\* OR warmup program\* OR the11)

AND

(football OR foot ball OR soccer)

### **Study selection**

For estimating the effect of the FIFA 11 programmes on injury rates we will only include randomised or cluster randomised controlled trials comparing the FIFA 11 prevention programmes with a control (no or sham intervention) among football players. To be included studies have to fulfil the following criteria: (1) Full-text paper published in peer-reviewed journal shall be available; (2) Contain original data from a randomised or a cluster randomised trial; (3) Evaluate the preventive effect of FIFA 11 or the FIFA 11+ programme; (4) Include football players only (5) Investigate football injury as the outcome.

Compliance to the FIFA 11 or the FIFA 11+ programmes will be investigated from the included randomised and/or cluster randomised studies.

In the search of possible adverse events reported in relation to actually performing the FIFA 11 programmes (adverse events experienced while performing the programmes), we will also include all other original studies or reports including practical execution of the FIFA 11 programmes. This

in order to look at possible adverse events related to the FIFA 11 programmes in football players. Possible adverse events will be reported as a secondary outcome in this systematic review.

Possible relevant studies, identified by titles and abstracts, from the search are downloaded into Reference Manager and duplicates are removed. Two authors (KT and KK) will independently perform the selection of studies based on the full references given by the bibliographic databases. This will be followed by full text evaluation of the selected studies from the first selection step. Disagreement between the two reviewers will be solved by consensus involving a third reviewer (EMB).

#### **Data extraction and risk of bias assessment**

Two reviewers (EE and MBC) will independently extract data using a specifically designed standardized data extracting form (Appendix 1) and compare the extracted data afterwards for consistency. All inconsistencies between the two forms will be resolved by discussion between the two data extractors. Any disagreement between the data extractors after the initial discussion related to inconsistencies between the two individual data extractions will be solved involving a third person (EMB). General study information, participants and intervention characteristics, compliance, adverse events, withdrawals and outcome measures will be extracted (Appendix 1). If data is not available from tables or the result section, the authors of the study in question will be contacted. Whenever possible, results from the intention-to-treat population will be used.

Included randomised and cluster-randomised studies will be assessed for risk of bias by two independent raters (EE and MBC) using the Cochrane Collaboration's tool for assessing risk of bias in randomised trials.<sup>15</sup> Each trial will be evaluated across seven domains of bias, including one or more items that are appraised in two parts. Firstly, the relevant trials' characteristics related to the item will be summarized. Secondly, each bias domain is judged as high or low risk of bias, according to their possible effect on the results of the trial. When the possible effect is unknown or insufficient detail is reported, the item is judged as unclear. All the above concerning risk of bias will follow the description in the Cochrane Handbook for Systematic Review of Interventions, version 5.1 (Part 2: 8.5.1).<sup>15</sup> When we assess risk of bias in cluster-randomised trials, particular types of bias are included in the "other bias" domain, according to how to assess risk of bias in cluster-randomised trials recommended in Cochrane Handbook for Systematic Review of Interventions, version 5.1 (Part 3: 16.3.2).<sup>15</sup> Any disagreements between ratings will be resolved by discussion between the raters. Consultation with a third party (EMB) will be used if disagreements still appear after this discussion. An assessment of the methodological quality will not be performed, as no evidence for such appraisals and judgements exists and therefore can be misleading when interpreting the results.<sup>15</sup> The use of quality scales and summary scores is considered problematic due to considerable variations between items and dimensions covered in these scales, with little evidence relating to the internal validity of these assessments.<sup>16</sup>

The risk of bias assessment includes the following seven domains: Random sequence generation (selection bias), Allocation concealment (selection bias), blinding of participants and researchers (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias), and other bias (including specific bias for cluster-designed studies). High risk of bias is to be expected from the domains concerning blinding of participants and researchers (performance bias), and blinding of outcome assessment (detection bias). This, because in prevention studies using active exercise programmes, such as the FIFA 11 programme, it is not possible to blind the participants from the intervention, or the outcome assessment as the reporting of injuries are self-reported by definition in such studies. Therefore, risk of bias assessment was followed as recommended by Cochrane Handbook for

Systematic Review of Interventions, version 5.1 (Part 2: 8.5.1)<sup>15</sup> and (Part 3: 16.3.2)<sup>15</sup> but not considered for sensitivity analyses in the final evaluation of the primary or the secondary outcome (The risk of bias assessment form can be seen in Appendix 2)

### **Primary outcome**

Overall injury incidence defined as the number of injuries per 1000 hours of football exposure. This includes all injuries (overuse and traumatic) sustained during the study period in both training and match.

### **Secondary Outcomes**

Overall injury incidence defined as the number of injuries per 1000 hours of football exposure. This includes all injuries (overuse and traumatic) sustained during the study period in both training and match.

Lower limb injury incidence defined as the number of lower limb injuries per 1000 hours of football exposure. This includes all lower limb injuries (overuse and traumatic) sustained during the study period in both training and match.

Region specific lower limb injury incidence for hamstring, knee and ankle, respectively, defined as the number of these injuries per 1000 hours of football exposure. This includes all injuries (overuse and traumatic) sustained during the study period for each of these regional injuries in both training and match.

Compliance to the intervention will be estimated as the number of FIFA prevention programme sessions performed during the intervention period divided by the length of the intervention period in months. The mean compliance for each study included in the primary analysis will be estimated from data available in the included trials. For the same trials the compliance for each individual team will be estimated from similar data, at team level, obtained directly from the authors of the original trials. Accordingly, data at team level will be obtained on: Total number of injuries; Total exposure time (hours); Number of FIFA prevention programme sessions performed, and the duration of the FIFA prevention programme exercise period (months). The first author of this systematic review (KT) will contact corresponding authors of all randomised and cluster randomised studies included in the primary analysis concerning these compliance/injury data, and ask them to provide this information in a pre-specified form on compliance and injury rates at team level (Appendix 3).

Reports on the number and type(s) of adverse effects related to the actual execution of the FIFA programmes (experienced while performing the prevention exercises) in relation to the number of players in the studies, will be reported.

### **Data synthesis and analyses**

#### **Primary analysis**

The incidence rate ratio (IRR) and 95% confidence intervals will be estimated as relative effect size using the extracted data on the overall injury incidence (typically reported as the total number of injuries per 1000 hours), as this is predefined as the primary outcome. If the injury incidence is not available in the published article the first author (KT) of the systematic review will send an email to the author(s) and ask for the data. If exposure is not available, we will use the number of injuries instead.



If cluster randomised trials provide a cluster-adjusted estimate, we will use it. If trials don't report the cluster-adjusted estimates we will use the intra-cluster correlations coefficient (ICC) from their own trial (if reported) or use the intra-cluster correlations coefficient (ICC) from similar trials to adjust for a potential cluster effect by calculating the inflation factor (IF). The equation for cluster adjustment is  $IF = 1 + (n-1)p$ , where  $p$  is the intraclass correlation coefficient,  $n$  the average cluster size and  $IF$  the inflation factor.<sup>15;17</sup> Effective sample size is calculated by dividing the number of injuries and amount of exposure hours with the  $IF$  as described in the Cochrane Handbook for Systematic Review of Interventions, version 5.1 (Part 3: 16.3.4).<sup>15</sup>

Review Manager version 5.3 (Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration) will be used when calculating the pooled IRR. A forest plot will be used to allow for easy visual comparisons between studies. The level of statistical heterogeneity for pooled data will be established using the  $\chi^2$  and  $I^2$  statistics. The  $\chi^2$  and  $I^2$  statistics describe heterogeneity or homogeneity of the comparisons with  $p < 0.05$  indicating a significant heterogeneity.<sup>18</sup> The Mantel-Haenszel<sup>19;20</sup> random effects method will be selected as default option.

### Secondary exploratory analyses

IRR and 95% confidence intervals will be estimated as relative effect size using the extracted data on the incidence of all lower limb injuries, and for overall injuries in the following subgroups: gender (male and female), and mean age groups (youth (<19 years), Senior (19-30 years), Old girls/boys (31-39 years), Veteran (>39 years)), and type of programme (FIFA 11 or FIFA 11+). If mean age is not provided, then median age will be used for the same age categories. The association between compliance to the programme and the injury incidence will be performed in two ways: one on study level and one on team level. The association between compliance and preventive effect will be analysed through estimating the association between the injury incidence from the individual studies and the average compliance in the individual studies using meta-regression analysis in Stata. To counteract a potential heterogeneous compliance between the teams in the individual studies, we will also estimate the association between the injury incidence and the compliance at team level using Poisson regression as previous done by Soligard et al (2010).<sup>21</sup> This analysis will only include teams randomised to the prevention intervention (meaning one of the FIFA programmes).

### Post-hoc analysis

Any other analysis deviating from the planned analyses will be considered post-hoc analysis.

### Implementation of statistical analyses plan

This statistical analyses plan (SAP) will be used as a work description for the person performing the statistical analyses (MSR). All analyses will be performed by the same person (MSR), and none of the other investigators involved in this trial will perform any of the statistical analyses. The implementation of the SAP will be as follows: 1. A "data extraction form" will be outlined in collaboration between the principal investigator (KT) and senior author (MSR). The authors involved in the data extraction (EE) and (MBC) will code each intervention arm into 'group A' and 'group B', for the statistical analyses. Data will be delivered by EE and MBC to MSR according to the "data extraction form". Primary and secondary analyses concerning the comparison of the two groups (intervention versus no or sham intervention) will be carried out using the same approach. Results will be presented by MSR to the writing committee of the systematic review (identical to all the other authors of this systematic review). The writing committee will then view the results of the analyses and thereby find out which of the pre-planned conclusions that should to be used in the first line of the conclusion in the manuscript (defined below). Any queries or disagreements concerning the conclusion in relation to the primary hypothesis will be discussed in the writing



committee and among all co-authors, and any final deviations from this will be specified in the discussion and conclusion section of the final manuscript and research publication. The primary hypothesis and the related pre-planned conclusion possibilities are outlined in the following section.

### **Primary hypothesis and pre-planned conclusion**

As our primary hypothesis is that the FIFA 11 programmes will reduce the overall injury rate compared to control (no or sham intervention) in football, we will test this hypothesis. One of three possible scenarios can be expected.

- 1) If the 95% confidence intervals (95%CI) of the incidence rate ratio (IRR) are below 1, and does not include 1, we will in the first line of the conclusion in both manuscript and abstract conclude that:

*An injury preventive effect of the FIFA 11 programmes compared to control (no or sham intervention) could be documented in football.*

- 2) If the 95% confidence intervals (95%CI) of the incidence rate ratio (IRR) include 1, we will in the first line of the conclusion in both manuscript and abstract conclude that:

*No injury preventive effect of the FIFA 11 programmes compared to control (no or sham intervention) could be documented in football.*

- 3) If the 95% confidence intervals (95%CI) of the incidence rate ratio (IRR) are above 1, and does not include 1, we will in the first line of the conclusion in both manuscript and abstract conclude that:

*In contrast to our hypothesis, that the FIFA 11 programmes compared to control (no or sham intervention) will reduce injuries, the data shows that the FIFA 11 programmes are associated with an increased number of injuries compared to control (no or sham intervention) in football.*

## Reference List

- (1) FIFA Communications Division. The Big Count. *FIFA Magazine* 2006.
- (2) Oja P, Titze S, Kokko S, Kujala UM, Heinonen A, Kelly P et al. Health benefits of different sport disciplines for adults: systematic review of observational and intervention studies with meta-analysis. *Br J Sports Med* 2015; 49(7):434-440.
- (3) Krustup P, Bangsbo J. Recreational football is effective in the treatment of non-communicable diseases. *Br J Sports Med* 2015 (Epub ahead of print).
- (4) Peterson L, Junge A, Chomiak J, Graf-Baumann T, Dvorak J. Incidence of football injuries and complaints in different age groups and skill-level groups. *Am J Sports Med* 2000; 28(5 Suppl):S51-S57.
- (5) Powell JW, Barber-Foss KD. Injury patterns in selected high school sports: a review of the 1995-1997 seasons. *J Athl Train* 1999; 34(3):277-284.
- (6) Bizzini M, Dvorak J. FIFA 11+: an effective programme to prevent football injuries in various player groups worldwide-a narrative review. *Br J Sports Med* 2015; 49(9):577-579.
- (7) Kisser R, Bauer B. The Burden of Sport Injuries in the European Union. *Austrian Road Safety Board* 2012.
- (8) Fédération Internationale de Football Association. Football for Health. *Zurich* 2010.
- (9) Junge A, Lamprecht M, Stamm H, Hasler H, Bizzini M, Tschopp M et al. Countrywide campaign to prevent soccer injuries in Swiss amateur players. *Am J Sports Med* 2011; 39(1):57-63.
- (10) Barengo NC, Meneses-Echavez JF, Ramirez-Velez R, Cohen DD, Tovar G, Bautista JE. The impact of the FIFA 11+ training program on injury prevention in football players: a systematic review. *Int J Environ Res Public Health* 2014; 11(11):11986-12000.
- (11) Soligard T, Myklebust G, Steffen K, Holme I, Silvers H, Bizzini M et al. Comprehensive warm-up programme to prevent injuries in young female footballers: cluster randomised controlled trial. *BMJ* 2008; 337:a2469.
- (12) Steffen K, Myklebust G, Olsen OE, Holme I, Bahr R. Preventing injuries in female youth football--a cluster-randomized controlled trial. *Scand J Med Sci Sports* 2008; 18(5):605-614.
- (13) Moher D, Liberati A, Tetzlaff J, Altman DG. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *J Clin Epidemiol* 2009; 62(10):1006-1012.
- (14) Dvorak J, Junge A, Grimm K. Football medicine manual. *Zurich: F-MARC* 2005.
- (15) Higgins JPT, Green S. Cochrane handbook for systematic reviews of interventions version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. <http://www.cochrane-handbook.org> 2015.

- (16) Juni P, Altman DG, Egger M. Systematic reviews in health care: Assessing the quality of controlled clinical trials. *BMJ* 2001; 323(7303):42-46.
- (17) Emery CA. Considering cluster analysis in sport medicine and injury prevention research. *Clin J Sport Med* 2007; 17(3):211-214.
- (18) Higgins JP, Thompson SG, Deeks JJ, Altman DG. Measuring inconsistency in meta-analyses. *BMJ* 2003; 327(7414):557-560.
- (19) Greenland S, Robins JM. Estimation of a common effect parameter from sparse follow-up data. *Biometrics* 1985; 41(1):55-68.
- (20) Mantel N, Haenszel W. Statistical aspects of the analysis of data from retrospective studies of disease. *J Natl Cancer Inst* 1959; 22(4):719-748.
- (21) Soligard T, Nilstad A, Steffen K, Myklebust G, Holme I, Dvorak J et al. Compliance with a comprehensive warm-up programme to prevent injuries in youth football. *Br J Sports Med* 2010; 44(11):787-793.

**APPENDIX 1:****DATA EXTRACTION FORM**

|                  |              |                      |
|------------------|--------------|----------------------|
| <b>Reviewer:</b> | <b>Date:</b> | <b>Study number:</b> |
|------------------|--------------|----------------------|

**GENERAL STUDY INFORMATION**

First author (e.g. Smith F):

Correspondence to:

☐ Detail not provided

Title:

Journal:

Year of publication:

Vol.:

Num.:

Pages:

Country:

Language:

Sources of support:

**STUDY DESIGN**☐ Randomised Controlled Trial☐ Cluster Randomised Controlled Trial☐ Not Randomised Trial (jump to non-randomised section)**Setting:** ☐ Unicenter☐ Multicenter (☐ National / ☐ International)☐ Detail not provided

Recruitment period (months):

☐ Detail not provided**STUDY POPULATION AND PARTICIPANTS**

Study population description:

Inclusion criteria:

Exclusion criteria:

| Flow of participants    |                                  |                   |
|-------------------------|----------------------------------|-------------------|
|                         | Groups<br>Intervention / Control | Reasons / Details |
| Invited to participate  |                                  |                   |
| Declined to participate |                                  |                   |
| Excluded                |                                  |                   |
| Randomized              |                                  |                   |
| Dropouts                |                                  |                   |
| Completed               |                                  |                   |
| Analysed                |                                  |                   |

| Baseline characteristics |                 |                       |                  |  |
|--------------------------|-----------------|-----------------------|------------------|--|
| Variables                | Total:<br>(n= ) | Intervention<br>(n= ) | Control<br>(n= ) | Between group difference<br>(statistically significant)  |
| Age ( )                  |                 |                       |                  | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Gender (M/F)             |                 |                       |                  | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Weight ( )               |                 |                       |                  | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Height ( )               |                 |                       |                  | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| BMI ( )                  |                 |                       |                  | <input type="checkbox"/> Yes <input type="checkbox"/> No |
|                          |                 |                       |                  | <input type="checkbox"/> Yes <input type="checkbox"/> No |

## INTERVENTION

Intervention general description and objectives:

Duration (weeks/months):

| Intervention characteristics |                                  |             |           |                  |
|------------------------------|----------------------------------|-------------|-----------|------------------|
| Group                        | Programme                        | Supervision | Frequency | Session duration |
| Intervention                 | <input type="checkbox"/> The 11  |             |           |                  |
|                              | <input type="checkbox"/> The 11+ |             |           |                  |
| Control                      |                                  |             |           |                  |

## DATA COLLECTION

Follow up (months):

Definition of injury: ☐ Yes ☐ No

**If yes:**

☐ Time loss

☐ Medical attention

☐ Other (describe):

| Data collection procedures          |                                     |                                     |                            |         |
|-------------------------------------|-------------------------------------|-------------------------------------|----------------------------|---------|
| Variables                           | Responsible<br>(who collected data) | Method<br>(scale, instrument, etc.) | Frequency of<br>collection | Details |
| Exposure time                       |                                     |                                     |                            |         |
| Number of injuries                  |                                     |                                     |                            |         |
| Characteristic of<br>injuries       |                                     |                                     |                            |         |
| Compliance with<br>the intervention |                                     |                                     |                            |         |
|                                     |                                     |                                     |                            |         |

**RESULTS**

| Drop-outs    |          |                     |
|--------------|----------|---------------------|
| Group        | Num. (%) | Description/Reasons |
| Total        |          |                     |
| Intervention |          |                     |
| Control      |          |                     |

| Exposure (h) |                |              |         |
|--------------|----------------|--------------|---------|
|              | Total exposure | Intervention | Control |
| Total        |                |              |         |
| Training     |                |              |         |
| Match        |                |              |         |

| Results on injury incidence including 95% confidence interval |                       |               |
|---|-----------------------|---------------|
|   | Intervention<br>(n= ) | Control (n= ) |
| Overall injury incidence                                      |                       |               |
| Lower limb injury incidence                                   |                       |               |
| Hamstrings injury   |                       |               |
| Knee injury incidence   |                       |               |
| Ankle injury incidence  |                       |               |

| Results on number of injuries |                |                       |                  |
|-------------------------------|----------------|-----------------------|------------------|
|                               | Total<br>(n= ) | Intervention<br>(n= ) | Control<br>(n= ) |
| Number of overall injuries    |                |                       |                  |
| Number of lower limb injuries |                |                       |                  |
| Number of hamstrings injuries |                |                       |                  |
| Number of knee injuries       |                |                       |                  |
| Number of ankle injuries      |                |                       |                  |

| Compliance   |                    |
|--|--------------------|
| Pre-defined compliance in the study: <input type="checkbox"/> Yes <input type="checkbox"/> No  |                    |
| If yes, describe:  |                    |
| Main descriptions of interest  | Intervention Group |
| Number of times that the prevention programme was performed during the intervention period   |                    |
| Proportion of preventive intervention sessions performed in relation to preventive intervention sessions initially planned (%)   |                    |
| Proportion of training/match sessions in which the preventive programme was performed in relation to the total number of training/match sessions during the intervention (%) |                    |
|  |                    |

## ADVERSE EVENTS

| Adverse events reported in relation to performing (during) the prevention programme |  |                     |
|---|--|---------------------|
| Registering adverse events  | <input type="checkbox"/> Yes <input type="checkbox"/> No |                     |
| Results   | Total:   | Intervention group: |
| Descriptions (type of adverse events, etc.):  |  |                     |

## CONCLUSIONS

| Conclusions      |  |
|------------------|--|
| Primary outcome: |  |

| COMMENTS                           |  |
|------------------------------------|--|
| (Add general comments if relevant) |  |



**METHODOLOGICAL DETAILS**

| Methodological details                     |   |                       |
|--|---|-----------------------|
|  |   | Description / details |
| <b>Eligibility criteria specified</b>      | <input type="checkbox"/> Yes <input type="checkbox"/> No  |                       |
| <b>Power calculation</b>                   | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not reported  |                       |
| <b>Estimated ICC for power calculation</b> | <input type="checkbox"/> Yes <input type="checkbox"/> No<br>(if yes, provide ICC value in description / details)  |                       |
| <b>Method of randomization</b>             | <input type="checkbox"/> Adequate / computer generated<br><input type="checkbox"/> Inadequate<br><input type="checkbox"/> Not reported  |                       |
| <b>Allocation concealment</b>              | <input type="checkbox"/> Adequate<br><input type="checkbox"/> Doubtful<br><input type="checkbox"/> Inadequate<br><input type="checkbox"/> Not reported  |                       |
| <b>Blinding</b>                            | Participants: <input type="checkbox"/> Yes <input type="checkbox"/> No<br>Therapist/s: <input type="checkbox"/> Yes <input type="checkbox"/> No<br>Outcome assessor/s: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not reported |                       |
| <b>Follow up</b>                           | Same duration for all players?<br><input type="checkbox"/> Yes (Duration:        months)<br><input type="checkbox"/> No (Mean duration:        months)<br><input type="checkbox"/> Not reported   |                       |
| <b>Handling of withdrawals description</b> | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not reported  |                       |
| <b>Intent to Treat</b>                     | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not reported  |                       |
| <b>Pre-published study protocol</b>        | <input type="checkbox"/> Yes <input type="checkbox"/> No  |                       |

| Additional data to be extracted for Cluster Randomised Controlled Trials |  | Description / details  |
|--|--|------------------------|
| <b>Taking clustering effects into account during analyses</b>            | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not reported                   |                        |
| <b>Reported ICC related to clustering effects</b>                        | <input type="checkbox"/> Yes <input type="checkbox"/> No<br>(if yes, provide ICC value in description / details) |                        |
| <b>Comparable clusters at baseline</b>                                   | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not reported                   |                        |
| <b>Recruitment after randomisation</b>                                   | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not reported                   |                        |
| <b>Number of clusters in control and intervention group</b>              | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not reported                   | Intervention   Control |
| <b>Average cluster size</b>  | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not reported                   | Intervention   Control |

**SECTION ONLY FOR NOT RANDOMISED TRIALS****STUDY POPULATION AND PARTICIPANTS**

Study population description:

| Baseline characteristics |                 |                       |                  |  |
|--------------------------|-----------------|-----------------------|------------------|--|
| Variables                | Total:<br>(n= ) | Intervention<br>(n= ) | Control (n=<br>) | Between group difference<br>(statistically significant)  |
| Age ( )                  |                 |                       |                  | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Gender (M/F)             |                 |                       |                  | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Weight ( )               |                 |                       |                  | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Height ( )               |                 |                       |                  | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| BMI ( )                  |                 |                       |                  | <input type="checkbox"/> Yes <input type="checkbox"/> No |
|                          |                 |                       |                  | <input type="checkbox"/> Yes <input type="checkbox"/> No |

**INTERVENTION**

Intervention general description and objectives:

Duration (weeks/months):

| Intervention characteristics |                                  |             |           |                  |
|------------------------------|----------------------------------|-------------|-----------|------------------|
| Group                        | Programme                        | Supervision | Frequency | Session duration |
| Intervention                 | <input type="checkbox"/> The 11  |             |           |                  |
|                              | <input type="checkbox"/> The 11+ |             |           |                  |
| Control                      |                                  |             |           |                  |

**ADVERSE EVENTS**

| Adverse events reported in relation to performing (during) the prevention programme |  |                     |
|---|--|---------------------|
| Registering adverse events  | <input type="checkbox"/> Yes <input type="checkbox"/> No |                     |
| Results   | Total:   | Intervention group: |
| Others descriptions:  |  |                     |

**COMMENTS***(Add general comments of the article if relevant)*

## APPENDIX 2:

## RISK OF BIAS ASSESSMENT FORM

Reviewer:

| First author (year):        (       )                       |   | Assessment data:     | Study number: |
|---|---|----------------------|---------------|
| Bias domain   | Author's judgment<br>(low, unclear, high) | Support for judgment |               |
| Random sequence generation (selection bias)                 |   |                      |               |
| Allocation concealment (selection bias)                     |   |                      |               |
| Blinding of participants and researchers (performance bias) |   |                      |               |
| Blinding of outcome assessment (detection bias)             |   |                      |               |
| Incomplete outcome data (attrition bias)                    |   |                      |               |
| Selective reporting (reporting bias)                        |   |                      |               |
| Other bias  |   |                      |               |

**APPENDIX 3:**

**REQUESTED INFORMATION FORM FROM CORRESPONDING AUTHORS  
OF ALL INCLUDED RANDOMISED OR CLUSTER RANDOMISED TRIALS  
(COMPLIANCE AND INJURY RATES AT TEAM LEVEL)**

| <b>Team_ID</b> | <b>Total number of injuries (overall)</b> | <b>Total exposure time (hours)</b> | <b>Number of FIFA 11/11+ sessions performed</b> | <b>Duration of the FIFA 11/11+ exercise period (months)</b> |
|----------------|---|------------------------------------|---|---|
|                |   |                                    |   |   |
|                |   |                                    |   |   |
|                |   |                                    |   |   |
|                |   |                                    |   |   |
|                |   |                                    |   |   |
|                |   |                                    |   |   |
|                |   |                                    |   |   |
|                |   |                                    |   |   |
|                |   |                                    |   |   |
|                |   |                                    |   |   |
|                |   |                                    |   |   |
|                |   |                                    |   |   |
|                |   |                                    |   |   |
|                |   |                                    |   |   |